

## REMARKS

Claims 8 to 13 are pending in the application.

### **Rejection under 35 U.S.C. 102**

Claims 8 and 11-13 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Brown (US 2003/0229514)*.

Claim 8 has been amended to define a medicament/dosimeter combination package that automatically dispenses a medication without intervention by the patient or physician. The combination package comprises a dosimeter containing a medicament to be individually dosed, wherein the dosimeter has a chip and dispensing means for the medicament. The combination package further comprises a diagnostic indicator system for a patient-specific property that is relevant for the action, side effect, interaction, metabolism, absorption, distribution, metabolism, and elimination of the medicament to be administered to a patient. The patient-specific property is selected from an endogenous substance, a regulation mechanism, a gene or an indication system. The diagnostic indicator system is comprised of a detector (e.g. strip or well) or chip with at least one reactive substance that when reacted with a bodily fluid provides information regarding the physiological or pathological state of the patient, the dosage of the medicament or both. The dosimeter and the diagnostic indicator system are interconnected and the information regarding the dosage is supplied to the dosimeter for dispensing the medicament in accordance with the information regarding the dosage.

The cited prior art discloses in claim 57 a health condition management apparatus that comprises a housing in which the following elements are disposed:

- a measuring device for measuring a health parameter;
- a compartment with medicine (refillable);
- a recording device for amount of administered medicine;
- a port for connecting to a computer;
- a display.

Such a management apparatus can be used in connection with treating diabetes and may comprise a syringe for injection of insulin (see claims 59 and 63). The specification of *Brown* discloses a patient unit 28 that is used for monitoring e.g. the glucose level. The administered amount of insulin can be recorded. The apparatus is used

for remote monitoring patients by connecting the monitoring unit 28 to a central computer and reading the measured values as well as the values of administered medication into the central computer for evaluation of the patient's health conditions and ongoing treatment. In addition the patient may be queried as to his current health condition and responses are sent to the central computer and added to the patient profile.

The disclosed system monitors patients (see Summary of the Invention) but does not actively provide means for determining and administering the quantity of medication that must be administered. As stated on page 9, right column, lines 19-23, the invention according to *Brown* "provides a powerful, convenient, and inexpensive system for remotely monitoring a large number of patients."

In the present invention as claimed in claim 8 the dosimeter and the diagnostic indicator system are interconnected and information regarding the dosage is supplied from the diagnostic indicator to the dosimeter for dispensing the medicament in accordance with the information regarding the dosage. The present invention provides an integrated and individual system of monitoring the patient and administering a medication in response to the measured patient data. This is disclosed in the specification on page 4, line 14, to page 5, line 6.

No such interconnected system is disclosed or suggested in *Brown*. *Brown* only teaches that a health care organization etc. can monitor a multitude of patients with regard to their test results, their personal subjective input in response to queries relating to their health condition, and in regard to the amount of medication the patients have administered themselves (according to a prescribed treatment regime). However, there is no disclosure that the measured data in regard to the glucose level are used by the management system to trigger the compartment holding the supply of medicine or the infusion device (syringe) to dispense an amount of medicine in accordance with the measured value. No interaction or interconnection between the measuring device and the compartment or infusion device (syringe) is disclosed. There is also no feedback to the patient from the central computer in regard to whether or not to take medication; increase or decrease the amount of medication etc. in response to the measured data. In particular, there is no interconnection so as to automatically trigger the dosimeter to dispense the medication as needed. The only feedback is the display that allows the patient to view the measured glucose data. The

patient then must make a determination whether to take or not to take insulin.

In contrast to this, an individualized therapy that is responsive instantly to measured patient's data is provided by the present invention.

Reconsideration and withdrawal of the rejection of claim 8 and its amended claims are therefore respectfully requested.

#### **Rejection under 35 U.S.C. 103**

Claims 9 to 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown and Phillips (US 5,843,692)*.

Claims 9 and 10 are believed to be allowable as dependent claims of claim 8.

#### **CONCLUSION**

In view of the foregoing, it is submitted that this application is now in condition for allowance and such allowance is respectfully solicited.

Should the Examiner have any further objections or suggestions, the undersigned would appreciate a phone call or **e-mail** from the examiner to discuss appropriate amendments to place the application into condition for allowance.

Authorization is herewith given to charge any fees or any shortages in any fees required during prosecution of this application and not paid by other means to Patent and Trademark Office deposit account 50-1199.

Respectfully submitted on April 14, 2008,

/Gudrun E. Hockett/

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